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I, JANENE PEISKER, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PR 1778 for a patent by COCHLEAR LIMITED as filed on 29 November 2000.

WITNESS my hand this
Nineteenth day of December 2005

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AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Tip structure for a cochlear implant electrode array carrier

The invention is described in the following statement:

Field of the Invention

The present invention relates to an implantable device and, in particular, to an implantable cochlear electrode assembly.

Background of the Invention

In many people who are profoundly deaf, the reason for deafness is absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, no matter how loud the acoustic stimulus is made, because there is damage to or an absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve. US Patent 4532930, the contents of which are incorporated herein by reference, provides a description of one type of traditional cochlear implant system.

Typically, cochlear implant systems have consisted of essentially two components, an external component commonly referred to as a processor unit and an internal implanted component commonly referred to as a stimulator/receiver unit. Traditionally, both of these components have cooperated together to provide the sound sensation to a user.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a sound processor that converts the detected sounds, particularly speech, into a coded signal, a power source such as a battery, and an external transmitter coil.

The coded signal output by the sound processor is transmitted transcutaneously to the implanted stimulator/receiver unit situated within a recess of the temporal bone of the user. This transcutaneous transmission occurs via the external transmitter coil which is positioned to communicate with an implanted receiver coil provided with the stimulator/receiver unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted stimulator/receiver unit. Conventionally, this link

has been in the form of an RF link, but other such links have been proposed and implemented with varying degrees of success.

The implanted stimulator/receiver unit traditionally includes a receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

Traditionally, the external componentry has been carried on the body of the user, such as in a pocket of the user's clothing, a belt pouch or in a harness, while the microphone has been mounted on a clip mounted behind the ear or on the lapel of the user.

More recently, due in the main to improvements in technology, the physical dimensions of the sound processor have been able to be reduced allowing for the external componentry to be housed in a small unit capable of being worn behind the ear of the user. This unit allows the microphone, power unit and the sound processor to be housed in a single unit capable of being discretely worn behind the ear, with the external transmitter coil still positioned on the side of the user's head to allow for the transmission of the coded sound signal from the sound processor and power to the implanted stimulator unit.

Together with improvements in available technology, much research has been undertaken in the area of understanding the way sound is naturally processed by the human auditory system. With such an increased understanding of how the cochlea naturally processes sounds of varying frequency and magnitude, there is a need to provide an improved cochlear implant system that delivers electrical stimulation to the auditory nerve in a way that takes into account the natural characteristics of the cochlea.

It is known in the art that the cochlea is tonotopically mapped. In other words, the cochlea can be partitioned into regions, with each region being responsive to signals in a particular frequency range. This property of the cochlea is exploited by providing the electrode assembly with an array of electrodes, each electrode being arranged and constructed to deliver a cochlea stimulating signal within a preselected frequency range to the appropriate cochlea region. The electrical currents and electric fields from each electrode

stimulate the cilia disposed on the modiolus of the cochlea. Several electrodes may be active simultaneously.

It has been found that in order for these electrodes to be effective, the magnitude of the currents flowing from these electrodes and the intensity of the corresponding electric fields, are a function of the distance between the electrodes and the modiolus. If this distance is relatively great, the threshold current magnitude must be larger than if the distance is relatively small. Moreover, the current from each electrode may flow in all directions, and the electrical fields corresponding to adjacent electrodes may overlap, thereby causing cross-electrode interference. In order to reduce the threshold stimulation amplitude and to eliminate cross-electrode interference, it is advisable to keep the distance between the electrode array and the modiolus as small as possible. This is best accomplished by providing the electrode array in the shape which generally follows the shape of the modiolus. Also, this way the delivery of the electrical stimulation to the auditory nerve is most effective as the electrode contacts are as close to the auditory nerves that are particularly responsive to selected pitches of sound waves.

In order to achieve this electrode array position close to the inside wall of the cochlea, the electrode array can be designed such that it assumes this position upon or immediately following insertion into the cochlea. This is a challenge as the array needs to be shaped such that it assumes a curved shape to conform with the shape of the modiolus and must also be shaped such that the insertion process causes minimal trauma to the sensitive structures of the cochlea. In this regard, it has been found to be desirable that the electrode array be generally straight during the insertion procedure.

Several procedures have been adopted to provide an electrode assembly that is relatively straightforward to insert while adopting a curved configuration following insertion in the cochlea. In developing electrode array designs, it is desirable that the design be constructed to minimise potential damage to sensitive structures in the cochlea on insertion and placement.

The present invention is directed to an electrode assembly constructed to minimise the likelihood of damage to structures in the cochlea on insertion and placement of the electrode assembly.

In providing the above description of the prior art, the present applicant is not conceding that any or all of the above description is part of

the present common general knowledge of a person skilled in the art of the present invention in Australia.

Summary of the Invention

According to a first aspect, the present invention is an implantable tissue-stimulating device including:

an elongate member having a body having a first end, the elongate member having a plurality of electrodes mounted thereon adapted to apply a preselected tissue stimulation; and

a resiliently flexible tip member extending forwardly from the first end of the body.

In one embodiment of the first aspect, the tissue-stimulating device can be a cochlear implant electrode assembly. The tip member in this embodiment can be constructed to assist in the guiding of the elongate member into the cochlea.

In a further embodiment, the elongate member can be straight or curved. The elongate member can be adapted to adopt a spiral configuration.

In a further embodiment, the elongate member can have a first configuration selected to allow said member to be inserted into an implantee's body and at least a second configuration wherein said elongate member is adapted to apply the preselected tissue stimulation. In a preferred embodiment, the second configuration of the elongate member is curved. More preferably, the elongate member adopts a spiral configuration when in the second configuration.

In a still further embodiment, the elongate member can have a receiving portion. The device can still further include a removable stiffening means positionable within the receiving portion of the elongate member and having a configuration selected for biassing said elongate member into said first configuration. The stiffening means is preferably relatively stiffer than said elongate member.

The elongate member can be formed from a resiliently flexible material.

The tip member preferably has a distal end and a proximal end.

In a further embodiment, the tip member has a relatively lesser stiffness than said stiffening means. In one embodiment, the tip member can be formed of a material having the substantially the same or the same stiffness as the body of the elongate member. In a further embodiment, the tip member can be formed of a material having a relatively lesser stiffness

than a portion of the body of the elongate member. In a further embodiment, the tip member can be formed of a material that undergoes a change in stiffness, preferably a decrease in stiffness, on insertion into the body, such as the cochlea.

In a further embodiment, the stiffness of the tip member can vary along at least a portion of its length from its distal end to its proximal end. In one embodiment, the stiffness of the tip member can vary over the entire length of the tip member or only a portion thereof. The stiffness can increase from the distal end to the proximal end. In one embodiment, the stiffness of the tip member over said portion or its length can increase gradually from its distal end towards to the proximal end. The increase in stiffness can be substantially smooth or increase in a stepwise fashion.

In a further embodiment, the tip member can be formed of the same material as the body of the elongate member. In another embodiment, the tip member can be formed of a different material to that of the body of the elongate member. The tip member can be comprised of an inner relatively stiff core of material having a tapered end, with at least the tapered end being overlaid by a relatively flexible material that extends beyond the tapered end of the core material so that the tip member undergoes a gradual decrease in flexibility in the region of the tapered end of the core moving away from the distal end.

The tip member can be formed separately to the body of the elongate member and mounted thereto. For example, the tip member can be adhered to the first end of the body of the elongate member. In another embodiment, the tip member can be integrally formed with the body of the elongate member. The tip member can be formed from a silicone material. In another embodiment, the tip member can be formed of an elastomeric material, such as polyurethane.

In another embodiment, the tip member can have a plurality of metallic particles dispersed therethrough. The metallic particles can be substantially evenly dispersed through the tip member. Alternatively, the metallic particles can be non-evenly dispersed throughout the tip member. In one embodiment, the metallic particles can increase in density away from the distal end towards the proximal end of the tip member. By varying the density of the metallic particles, it is possible to vary the relative stiffness of the tip member.

The metallic particles preferably comprise a biocompatible material, such as platinum. The particles can be substantially spherical or spherical. It will be appreciated that the particles can have other suitable shapes. In one embodiment, the particles can have a diameter between about 50μm and 100μm.

In addition to, or instead of, being used to potentially modify the physical characteristics of the tip member, the provision of the metallic particles also result in the tip member being detectable by fluoroscopy and X-ray techniques. This provides another means for the surgeon to either monitor the placement and position of the tip member during or after insertion of the electrode array in the body, such as in the cochlea.

When the elongate member is in the first configuration, the tip member is preferably substantially straight and, more preferably, straight.

In a further embodiment, the tip member can be coated with a lubricious material. The lubricious material can be a bioresorbable or non-bioresorbable material.

The tip member can be formed from, or incorporate as a portion thereof, a bioresorbable material. The presence of the bioresorbable material preferably results in the flexibility of the tip member increasing on insertion of the tip member into the body, such as the cochlea. The bioresorbable material in the tip member can be selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

In another embodiment, the tip member can be formed from, or incorporate as a portion thereof, a polymeric coating which becomes softer, and so increases in resilient flexibility, in the presence of moisture or body heat.

The tip member preferably has a length from its distal end to its proximal end in the range of about 0.3 to 4mm, more preferably about 1.0 to 3mm. The diameter of the tip member can be substantially constant for a majority of its length or can vary in diameter. The tip member can be substantially cylindrical, cylindrical, or non-cylindrical for a majority of its length. At the distal end, the diameter preferably gradually decreases to form a rounded end. The maximum diameter of the tip member is preferably about 0.55mm.

In one embodiment, the tip member can be solid. In another embodiment, the tip member can have an external wall defining a cavity. In one embodiment, the cavity can have a diameter greater than that of the receiving portion of the body of the elongate member. In a further embodiment, the cavity can extend from the proximal end towards the distal end of the tip member. The cavity can decrease in diameter away from the proximal end. The cavity can be in communication with a distal end of the receiving portion of the body of the elongate member. In a further embodiment, the stiffening means can extend into the cavity when positioned within the device or assembly according to the respective aspects of the present invention. In a preferred embodiment, the tip member can move relative to the stiffening means when it extends into the cavity of the tip member.

In general, the tip could be made of a combination of materials arranged in a variety of geometries depending on the specific design goal. The outside shape and size of the tip can also be made in a variety of forms depending on the design goal.

The body of the elongate member is preferably preformed from a plastics material with memory and is preformed to the second configuration.

In a preferred embodiment, the first configuration is preferably substantially straight. More preferably, the first configuration is straight.

In a preferred embodiment, the body of the elongate member is formed from a suitable biocompatible material. In one embodiment, the material can be a silicone. In another embodiment, the body can be formed from a suitable elastomeric material, such as a polyurethane.

In one embodiment, the stiffening means is formed of a bioresorbable material which dissolves on exposure to a fluid. The stiffening means can dissolve on exposure to a saline solution or a body fluid of the implantee, such as cochlear fluid.

In a further embodiment, the bioresorbable material of the stiffening means is selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

In another embodiment, the stiffening means can comprise a stiffening element formed from a non-bioresorbable material. In this embodiment, the stiffening element can comprise a metallic stylet extending through the receiving portion of the body of the elongate member. In one embodiment,

the wire can be formed from a biocompatible metal or metallic alloy. In a preferred embodiment, the metal stylet can be formed from platinum.

In a still further embodiment, the stiffening element can be formed from a shape memory or heat sensitive material. For example, the stiffening element can be formed from a bimetallic element (such as nickel/titanium) and shaped to take a straight or substantially straight configuration at room temperature but bends into another shape once it is exposed to body temperature.

In one embodiment, the receiving portion can comprise a lumen extending at least into, and more preferably through, the body of the elongate member. The lumen for the stylet can be cylindrical and also can have an opening formed therein distal the tip member. In the case of a metal stylet, the stylet can extend out of the opening allowing the stylet to be manipulated and removed from the lumen during or following insertion of the device. In the case of a bioresorbable stiffening element, the opening can act as a fluid ingress means allowing body fluids to enter the lumen on insertion of the device into an implantee.

The assembly or device according to the respective aspects of the invention can further include a stiffening sheath that envelops the elongate member. The sheath can be made of a material that is relatively stiffer than the material of the body of the elongate member. Where used, the stiffening sheath can, in combination with the stiffening element, act to bias the elongate member into the first configuration. Removal of either the element or sheath, in this embodiment, preferably results in the elongate member adopting an intermediate configuration between the first and second configurations.

Where the stiffening means is a metallic or metallic alloy stylet, the stiffening sheath is preferably formed of a bioresorbable material which dissolves on exposure to a fluid. The stiffening sheath can dissolve on exposure to a saline solution or a body fluid of the implantee, such as cochlear fluid.

In a further embodiment, the bioresorbable material of the stiffening sheath is selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

The device can include an additional layer surrounding the stiffening sheath. The additional layer can have a first rate of fluid ingress therethrough

and have at least one fluid ingress means formed therein, the rate of fluid ingress through the fluid ingress means being greater than the first rate of fluid ingress through the additional layer.

The fluid ingress means can comprise one or more openings in the additional layer. The openings can be closable. The openings can comprise slits in the additional layer. The slits can be formed to allow substantially the same or the same rate of ingress of fluid through the additional layer. In another embodiment, at least one slit can allow a different rate of progress of fluid through the additional layer compared to the other slits.

Where the stiffening element is a metal or bioresorbable stylet, the stiffening sheath can, in one embodiment, be formed from a shape memory or heat sensitive material. For example, the stiffening sheath can be formed from a bimetallic filament (such as nickel/titanium) and shaped to take a maintain the straight or substantially straight configuration of the elongate member at room temperature but bends it into another shape once it is exposed to body temperature.

While both the stiffening element and the stiffening sheath are in position within the device, it will retain the first configuration, which as discussed is preferably straight. If the stiffening sheath is removed, whether it is by dissolution or otherwise, the remaining stiffening element preferably has insufficient strength to retain the elongate member in its first configuration. It is preferred that the elongate member, on removal of the stiffening sheath, will adopt an intermediate configuration in which the elongate member has at least some curvature. On subsequent removal of the stiffening element, the elongate member is free to adopt the fully curved second configuration desired of an implant for insertion into the cochlea.

The construction of the electrode assembly of the present invention is adapted to minimise the likelihood of trauma to the cochlea caused by electrode assembly insertion. The construction of the tip is envisaged by the present inventors to assist in guiding the electrode down the lumen of the scala tympani of the cochlea. It is also envisaged that it will minimise the potential for the tip of the electrode to perforate the basilar membrane of the cochlea or damage other sensitive structures in the cochlea.

Brief Description of the Drawings

By way of example only, one embodiment of the invention is now described with reference to the accompanying drawing, in which:

Fig. 1 is a simplified cross-sectional view of one embodiment of an electrode assembly according to the present invention depicted in its first configuration; and

Figs 2a, 2b, 2c and 2d depict some alternative tip structures for the electrode assembly to that depicted in Fig. 1.

Preferred Mode of Carrying Out the Invention

One embodiment of a cochlear implant electrode assembly according to the present invention is depicted generally as 10 in the drawings.

The assembly 10 comprises an elongate electrode carrier member 11. For the purposes of clarity, the plurality of electrodes that would be mounted on the carrier member 11 are not depicted in the attached drawings.

The depicted elongate member 11 is preformed from a resiliently flexible silicone with memory and is preformed to a curved configuration (not depicted) suitable for insertion in the scala tympani of the cochlea. The elongate carrier member 11 has a first end 13 that is firstly inserted into the implantee on insertion of the assembly 10.

In Fig. 1, a straight tip member 19 is shown integrally formed with the first end 13 of the carrier member 11. The tip member 19 extends forwardly from the first end 13 of the member 11 to a distal end 21. The tip 19 is formed from the same silicone used to fabricate the elongate member 11 and, in the depicted embodiment, the material of the tip member 19 has a resilient flexibility equal to that of the material used for the carrier member 11.

Disposed within a substantially cylindrical lumen 14 is a substantially straight platinum stylet 15. The depicted stylet 15 has a stiffness that is sufficient to retain the silicone elongate member 11 in a straight configuration when in the position depicted in Fig. 1.

As depicted, the stylet 15, when initially placed, can extend at least partially into a cavity 22 formed within the tip member 19. The dimensions of the cavity 22 relative to the diameter of the stylet 15 are such that the tip member 19 can move relative to stylet 15.

While a platinum stylet is depicted, a bioresorbable stylet formed from a bioresorbable polyacrylic acid (PAA) that is adapted to dissolve on exposure to cochlear fluids could be utilised with appropriate modification to the elongate carrier member 11. It will be appreciated that a bioresorbable stylet could be formed from other suitable bioresorbable materials. A stylet made

from a shape memory or heat sensitive material could also be utilised as stylet 15.

While not depicted, a stiffening sheath of bioresorbable material could overlay the depicted elongate member 11. The bioresorbable material of the stiffening sheath could be formed from PAA that is adapted to dissolve on exposure to cochlear fluids. Other suitable bioresorbable materials can again be envisaged.

While the elongate member 11 is manufactured with a preformed curved configuration, the assembly 10 is typically delivered to a surgeon with the stylet 15 in place, as depicted in Fig. 1.

On insertion into the scala tympani of the cochlea, the tip member 19 serves to help guide the carrier member 11 into the scala tympani of the cochlea. Being more flexible than the overall assembly 10, defined by member 11 and stylet 15, the tip member 19 more easily bends towards the open lumen of the scala tympani thus minimising the potential for the array to pierce sensitive structures of the cochlea.

The tip member 19 also serves to reduce the pressure generated at the tip of the electrode assembly as it is being inserted into the cochlea. This serves to help reduce the likelihood that the first end 13 of the elongate member 11 will be inadvertently forced through the basilar membrane of the cochlea on insertion.

Once or as the elongate member 11 is fed into the cochlea, the surgeon can withdraw the platinum stylet 15 through opening 17 of the lumen 14 at end 18. On withdrawal of the stylet 15, the elongate member 11 is free to adopt a spiral configuration with the electrodes facing the modiolus within the cochlea so that they are positioned as close as possible to the spiral ganglia thereof.

Possible alternatives for the construction of the tip member 19 are depicted in Figs. 2a, 2b, 2c and 2d. For example, as depicted in Fig. 2a, the tip member 30 can be solid and formed of an inner core 31 of relatively stiff material and an outer layer 32 of relatively flexible material. The core 31 can taper in diameter over region 33 towards the distal end 21. The taper 33 causes the overall stiffness of the tip 30 to increase over the length of the taper 33 away from the distal end 21. The outer layer 32 can be formed of the same material as the remainder of the body of the elongate carrier member 11 or can be a different material.

As depicted in Fig. 2b, the tip member 40 can comprise a solid mass integrally formed to the first end 13 of the elongate carrier 11.

Still further and as depicted in Fig. 2c, the tip member 50 can comprise a solid mass 51 that is formed separately from the carrier member 11 and subsequently adhered thereto.

As depicted in Fig. 2d, the tip member 60 can comprise an elastomeric silicone material having a plurality of substantially spherical platinum particles 61 dispersed therethrough. The particles 61 have a diameter between about 50μm and 100μm. It will be appreciated that the particles 61 depicted in Fig. 2d are not drawn to scale.

In Fig. 2d, the particles 61 are depicted as substantially evenly dispersed through the tip member 60. In another embodiment, the particles could be non-evenly dispersed through the tip member. For example, the particles could increase in density away from the distal end 21 towards the proximal end of the tip member 60. By varying the density of the platinum particles 61, it is possible to vary the relative stiffness of the tip member 60.

In addition to, or instead of, being used to potentially modify the physical characteristics of the tip member, the provision of the metallic particles 61 also result in the tip member 60 being detectable by fluoroscopy and X-ray techniques. This provides another means for the surgeon to either monitor the placement and position of the tip member 60 during or after insertion of the electrode array 10 in an implantee's cochlea.

While the preferred embodiment of the invention has been described in conjunction with a cochlear implant, it is to be understood that the present invention has wider application to other implantable electrodes, such as electrodes used with pacemakers.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

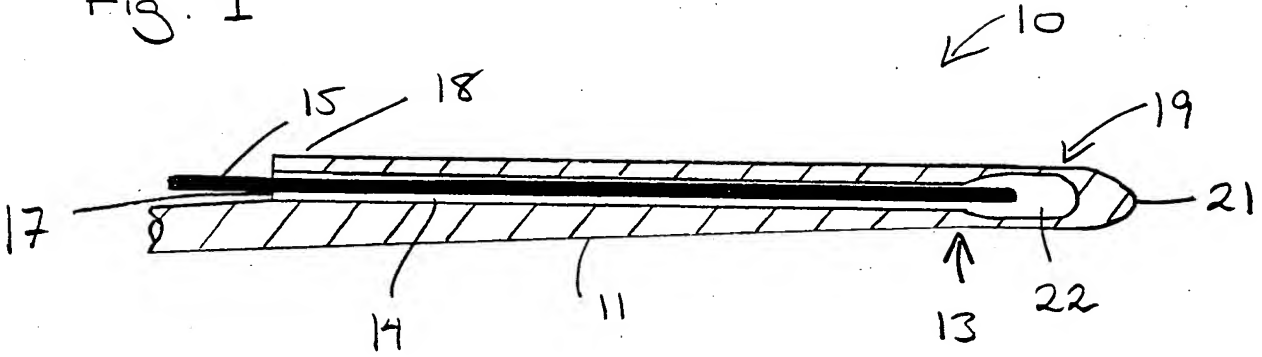
Dated this twenty-ninth day of November 2000

Cochlear Limited

Patent Attorneys for the Applicant:

F B RICE & CO

Fig. 1



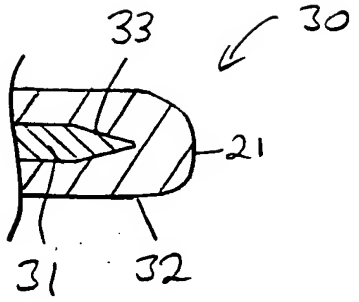


Fig. 2a

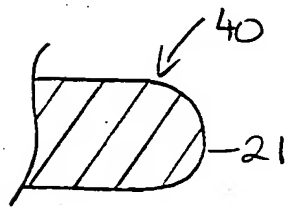


Fig. 2b

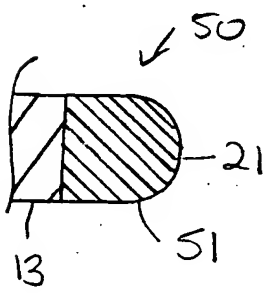


Fig. 2c

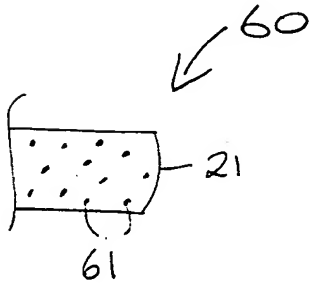


Fig. 2d